

DATA SUBMISSION

SWOG has developed a set of data collection forms for use with group protocols. Common forms are used for all patients on a particular study to ensure that data required for patient evaluation and study analysis are recorded in a systematic fashion. Some forms, such as onstudy forms, are designed to collect data common to a particular disease site. Others, such as treatment and adverse event forms, are specific to a particular study.

Forms to be submitted for a study are identified in the Data Submission Schedule (Section 14) of the protocol. Always consult the protocol for study specific requirements before submitting data. When in doubt, call the Statistics and Data Management Center (SDMC) for clarification. Intergroup studies generally use different forms and data submission requirements are determined by the coordinating cooperative group.

The majority of SWOG studies require an Onstudy form, study-specific Treatment and Adverse Event Forms, an Off Treatment Notice and a Notice of Death to be submitted at the intervals stated in the protocol. Additional forms may be required when response assessment or radiation therapy are part of the protocol treatment, or when surgery is required. Sometimes special forms designed to answer a specific question, are required.

Online Data Submission for SWOG studies activated April 1, 2012 to present

For SWOG studies activated after April 1, 2012, master forms are no longer included in the protocol however they can be found on the protocol abstract page on the SWOG website www.swog.org (with the exception of the sample consent form).

SWOG institutions must submit data electronically via the Web using Medidata Rave® at the following URL: <https://login.imedidata.com/selectlogin>

1. If prompted, select the 'CTEP-IAM ID' link.
2. Enter your valid and active CTEP-IAM username and password. This is the same account used for the CTSU members' web site and OPEN.

You may also access Rave® via the SWOG CRA Workbench located in the members section of www.swog.org.

If source documents are required they must be saved as .pdf files and uploaded to the appropriate folder in the Medidata Rave® chart.

Online Data Submission for SWOG studies activated prior to March 31, 2012

SWOG enforces mandatory online data submission for all studies activated after May 1, 2003. For older studies, online data is required where available. Certain items of data, such as pathology or operative reports should be submitted as hard copies.

Oncology Research Professionals (ORPs) can find links and instructions for online data submission at the CRA Workbench, which is located in the members section of www.swog.org. Online data submission is strongly encouraged for the following reasons:

1. The data is received and entered immediately at the SDMC, omitting mailing, processing and entry delays.
2. Any applicable expectations are resolved immediately upon receipt.
3. The most current version of the form will always be the one posted on the web.
4. Error checks are built in to the forms so that the user has a chance to catch incorrect patient identifiers, or correct simple inconsistencies, thereby avoiding rejected data or later queries for clarification.

After the form has been submitted and accepted by the SDMC database, a confirmation page will display which is a copy of the form with the submitted data and the user's name, date and time of submission. The ORP is expected to print a copy of this confirmation page for their local research records. Forms submitted prior to October 2010 cannot be amended online. Amendments to these forms must be made on the printed hard-copy of the form, and e-mailed or faxed to the SDMC. Forms completed October 2010 and later are amendable on-line. Each form has a header that explains whether or not the form is amendable on line.

Each ORP must be given permission by his or her Web User Administrator (WUA) to submit data online before he or she will be able to access any of the forms.

The Confirmation of Registration

The Confirmation of Registration is generated by the OPEN Registration program at the time of registration. Member institutions should forward a copy of the appropriate confirmations to the Affiliate investigators. ORPs) should review the Confirmation of Registration carefully to verify its accuracy and record the expectation due dates for future action. The SDMC should be notified immediately of inaccuracies that require correction. A copy of the Confirmation of Registration should be filed in the institutional patient research record for reference.

The Confirmation of Registration ([Figure 1](#)) includes patient demographic information, investigator and institution numbers, pertinent dates, stratification information, the patient number, the treatment assignment and answers to specimen consent questions, if applicable. A list of expectations for submitting specific forms and materials also appears on the Confirmation of Registration. The data in this list that is due within 15 days after the registration date comprises what is called the Initial Forms Set (IFS).

Figure 1

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Step 1 Registration Information: [Tracking # **176865**]

Protocol Number: S1318	Protocol Title									
Patient ID: 251825	A Phase II Study of Blinatumomab (NSC-765986) and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients >= 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib (NSC-732517), Prednisone and Blinatumomab for Patients >= 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL									
Initials (LFM): CCC										
Treatment Arm: 1 Ph+										
Registration Step: 1										
Institution: Bushmill Hematology Oncology PC [MA111]										
Registration Status: REGISTERED on 09/26/2014 04:50 PM EDT										
Associated Persons:	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Person Type</th> <th style="width: 40%;">Person Name</th> <th style="width: 30%;">Status</th> </tr> </thead> <tbody> <tr> <td>Treating Investigator</td> <td> D, Michael (15999)</td> <td>ACTIVE</td> </tr> <tr> <td>Site Registrar</td> <td> D, Michael (15999)</td> <td>ACTIVE</td> </tr> </tbody> </table>	Person Type	Person Name	Status	Treating Investigator	D, Michael (15999)	ACTIVE	Site Registrar	D, Michael (15999)	ACTIVE
Person Type	Person Name	Status								
Treating Investigator	D, Michael (15999)	ACTIVE								
Site Registrar	D, Michael (15999)	ACTIVE								
Drug Shipping Address:	Dr. Michael J D c/o Angela Griffiths Bushmill Hematology Oncology PC 916 Hamilton Drive Third Floor Peabody MA 01201 US									
Registration Initiated By:	RIVERSY on 09/26/2014 04:48 PM EDT									
Updated By:	RIVERSY on 09/26/2014 04:53 PM EDT									

Registration/Randomization details from Network Group

Eligibility: ELIGIBLE

Reason: None.

Assigned Treatment: 1 Ph+ = Induction: Ph-positive

Study End Notes

Attention CRA: this study will use the Medidata Rave software application for all data submission. More information about how to access Rave can be found in the protocol document and on the CRA Workbench.

Expectations for this registration

Instructions: BASEAB - Baseline Abnormalities form - S1318 Baseline Abnormalities -- Posted: 09/26/2014 - Due: 10/03/2014
DISASS - Disease Assessment Form - S1318 Baseline Dz Assessment -- Posted: 09/26/2014 - Due: 10/03/2014
ONSTUDY - Onstudy form - S1318 Onstudy Form -- Posted: 09/26/2014 - Due: 10/03/2014
SXPATHTQ - Pre-reg Pathology Report - See Section 14.4a -- Posted: 09/26/2014 - Due: 10/03/2014
BLOODSB - Blood submission - See Section 15.2 -- Posted: 09/26/2014 - Due: 10/10/2014
BMREP1 - BM to Repository - See Section 15.2 -- Posted: 09/26/2014 - Due: 10/10/2014
SERUM - Serum submission - See section 15.2 -- Posted: 09/26/2014 - Due: 10/10/2014

The Initial Forms Set (IFS)

The Initial Forms Set (IFS) must be received by the SDMC within 15 days after patient registration. Generally, the IFS consist of the following materials:

- Onstudy Form
- Ancillary Forms required by the protocol
- Baseline Tumor Assessment Form
- Baseline Abnormalities Form
- Pathology/Cytology Report
- Radiology reports from all scans performed to assess disease at baseline

The IFS due date(s) found on the Confirmation of Registration reflect the 15-day submission requirement.

The IFS submitted for each patient registered to a SWOG protocol is subjected to a quality control review by a data coordinator. The purpose of this review is to: (1) confirm the eligibility of the patient, (2) verify the stratification and descriptive factors, and (3) determine if the treatment was given and documented correctly. At the conclusion of this process, a Query Report (see [Figure 2](#)) will be listed on the CRA Workbench requesting any changes or additions needed for the IFS. For studies activated April 1, 2012 to present, requests for changes and/or additional data will be located in the Medidata Rave® application. Institutions can look up their ineligible patients via the CRA Workbench listed under “Reports”.

The Onstudy Form documents basic patient characteristics, disease history, the extent of disease at the time of registration, prior treatment, and the results of some pre-treatment laboratory tests. Onstudy forms are disease site specific, and will be included in the forms section of the particular protocol.

The Baseline Abnormalities Form should not be used to document the patient history, but should be limited to any conditions present at the time of registration, i.e. lab values that are out of range, current cardiac function deficit, etc. This can be used to assess changes in these conditions or new events that occur during treatment that should be documented as adverse events. See [Chapter 15](#) for more information.

The Baseline Tumor Assessment Form is designed to collect specific information regarding all sites with measurable and/or non-measurable disease. Please see [Chapter 16](#) of this manual for examples of Standard Baseline Tumor Assessment Form or others that may be specific to disease site.

Initial Quality Control

The quality control procedures help to ensure consistency in data submission among all SWOG institutions and provide feedback to the institutions if problems arise. Quality control checks are built into all aspects of data collection at the SDMC, and verification of data occurs on the following levels:

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- Review of new protocols and forms.
- Automatic consistency checks in data entry and registration programs.
- Review of pathology, surgery and radiation therapy by discipline reviewers.
- Review of data by protocol study chairs.
- Review of data by data coordinators.

The quality control procedure most visible to the ORP is the IFS review. SDMC Data Coordinators perform a quality control check on the IFS for every patient registered to a SWOG coordinated protocol.

The purpose of this quality control review is to confirm that patients are eligible, properly stratified and treated according to protocol requirements and it is performed using the following criteria:

1. The correct onstudy form must be used and the data on the form must support patient eligibility and stratification. If any item on the onstudy form conflicts with eligibility requirements, the data coordinator will request clarification from the registering institution using the Query Report. If the conflict is not satisfactorily resolved, the patient may be considered ineligible. Patients who are incorrectly stratified at registration will be considered ineligible if the correct stratum was closed at the time of registration or the incorrect stratification caused improper treatment assignment. The data coordinator will recalculate the patient's body surface area (BSA). If the institution has incorrectly calculated BSA, the data coordinator will bring it to the institution's attention if the discrepancy resulted in a significant dosage error (>10% dose deviation).
2. Some studies require submission of additional forms such as Operative Reports, Pathology reports, baseline tumor assessment forms, etc. to supply documentation of eligibility and stratification. The information on these forms must support eligibility and stratification. Requests, if any, are noted on the Query Report. All problems noted on the report must be resolved by the registering institution. As of September 1st, 2013, when responding to a request on a Query Report, the CRA must click on the RESOLVED button to the right of the request. ([Figure 2](#)). For studies activated April 1, 2012 to present, requests can be found in the Medidata Rave® application.
3. Amended information (circled, initialed and dated) must be submitted on the appropriate form (i.e., confirmation of registration, treatment) or by correcting the editable version of an on-line form. Since the Query Report is not part of the permanent patient record, it cannot be used as documentation. For studies activated April 1, 2012 to present, amended data will be handled directly in the Medidata Rave® application.

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Figure 2

- [Patient Info](#) [Forms](#) [Expectations](#) [Queries](#)

The following queries require your response as soon as possible. If the query is for an online amendable form please make those changes online. If the query is for data that is not available to amend online, please submit the requested data by fax **without a cover sheet** to the SWOG Data Operations Center at 800-892-4007. PLEASE NOTE: Even if you don't have corrections for every page of a form that prints out, please send ALL pages of the form **and** include patient initials and SWOG patient number on every page.

The query will display on both the queries tab and query report until you have responded to the request and clicked the 'Resolved' button below.

Any questions should be directed to the Data Coordinator for this study at 206-652-2267. If the Note Type says 'CRA' or 'ELIG, these are for informational purposes only and do not necessarily require your response. CRA notes may be removed by clicking the 'Acknowledged' button.

[Please Note: Replies written on a printout of this page are NOT acceptable documentation.](#)

S1117 Data Coordinator: Tracy Maher

<u>Note Date</u>	<u>Author</u>	<u>Note Type</u>	<u>Note</u>	
8/10/2014	TM	REQ	Please submit path report form marrow differential done 2/7/2014. We received cytogenetics and FISH reports only.	<input type="button" value="Resolved"/>
8/10/2014	TM	REQ	Please submit Transfusion Logs for each cycle of treatment. If transfusions not done during a cycle, just answer 'No' to that question, but each cycle must be documented	<input type="button" value="Resolved"/>
8/10/2014	TM	REQ	Please see Section 14.4c of protocol - S1117 Disease Assessment form should be submitted after each cycle documenting blood counts.	<input type="button" value="Resolved"/>
8/10/2014	TM	ELIG	Considered ineligible until pre-reg path report received.	

Subsequent Evaluation

After the initial quality control evaluation, the data coordinator conducts interim evaluations as data is submitted by the institution according to data submission requirements of the protocol. At particular points in the study, the patient's data is evaluated, and evaluation forms containing the current patient information are sent to the study chair. The study chair reviews the patient evaluation and returns the form to the SDMC. If omissions or discrepancies are noted in the patient data, a query will be generated requesting clarification. The ORP should amend or provide the requested data and resolve the query by clicking the RESOLVED button. For studies activated April 1, 2012 to present, query requests will be located in the Medidata Rave® application.

Query notes

The data coordinator adds notes to the SDMC database which appear on the Query Report to request additional items or elaborate on patient data. Some notes are simply informational, while other notes may request specific information.

Each note is preceded by identifying information:

- type -- the code used to describe the purpose of the note (see below)
- date -- the date the note was written
- who -- the author's initials
- number -- the number of the note

Note types:

CRA	Provides information for the Clinical Research Associate.
ELIG	A statement regarding patient's eligibility status for study – does not require a response from Institution
REQ	Requests information from the institution that is needed for eligibility verification or evaluation purposes.

Additional Information:

- When submitting data in response to a note requesting information, the ORP should resolve the query online by clicking on the RESOLVED button to the right of the query. For studies activated April 1, 2012 to present, data responding to a note requesting information should be submitted via the Medidata Rave® application.
- If information contained in the note is unclear, the ORP can contact the data coordinator (see the above initials) at the SDMC for clarification.

Note authors:

The following is a list of data coordinators at the SDMC:

AJ	Amy Johnson
BHZ	Brian Zeller
CMM	Christine Magner
DL	Diane Liggett
GH	Gabi Herbert
HH	Hannah Hale
IS	Iris Syquia
KC	Kimberly Carvalho
LGK	Larry Kaye
LLK	Laura Kingsbury
LW	Laura Wells
LE	Leah Everhart
LH	Louise Highleyman
ME	Mathew Eng
MC	Michele Counts
MY	Monica Yee
RT	Roxanne Topacio
SD	Sam Dzingle
TJ	Tonya Johnson
TM	Tracy Maher
ZG	Zoie Green

Data Submission Timeframes

The initial forms set (IFS) must be received at the SDMC within 15 days after patient registration.

Subsequent **On-Treatment Forms** must also be submitted within 15 days after each cycle or according to the data submission section of the study protocol; section 14.

The **Off Treatment Notice** is submitted when a patient goes off the treatment specified for the registration step, when treatment has been completed per protocol, or when one of the requirements for patient removal from protocol treatment is met. This form must be submitted within 30 days of the decision to take the patient off treatment.

After a patient is removed from protocol treatment, a study **Follow-Up Form** must be submitted every six months for two years and annually thereafter unless otherwise specified in the protocol. The Follow-Up Form will be overdue 30 days after the calendared date when follow up is expected. Persistent adverse events can be noted on the Follow-up form as well.

A **Notice of Death** and a final **Follow-Up Form** documenting circumstances and cause of death are submitted within 30 days of learning of a patient's death.

The timeframes noted above for data submission were adjusted for new activations in mid-2018 to be consistent with those set forth by the NCTN. Enrollments that occurred prior to this will have expectations posted that are more stringent.

Additional Data Submission Guidelines:

- For forms originally submitted on paper, write "amended" at the top of amended forms and mark amended data and circle. Draw a line through the incorrect entry, write the correction next to it then initial and date the change.
- For pre-Rave® studies, click the RESOLVED button to the right when responding to a request. To resolve a CRA, or informational note, click the ACKNOWLEDGED button.
- Do not write replies, updates or corrections on the SWOG Query Reports, they are not part of the permanent record and cannot be used as documentation.
- Ensure that uploaded source documents or faxed photocopies are legible and have correct patient identification on every page. At minimum, the SWOG Patient ID must be on every page for pre-Rave® studies and on at least one page in an uploaded PDF in Rave®. Illegible and/or unidentifiable copies will be returned to the institution or requested to delete and upload a clearer copy in Rave®. Any report submitted with specimens must also have the same labeling standards as uploaded data where the correct patient identification including SWOG study and patient number must be present on every page.
- Whenever possible, source documents written in a language other than English must be translated prior to submission. Some studies might accept the submission of a translated summary form. Always refer to section 14 of the protocol to verify study requirements. If no guidance is provided, contact the SDMC at 206-652-2267 and ask to speak to the responsible Data Coordinator to advise.
- Refrain from the use of correction fluid or tape. Data is now stored as electronic images so any changes must be clearly noted as indicated above.
- Do not use a highlighter; it doesn't fax or scan well and can obscure the data.
- Carefully redact all Protected Health Information (**PHI**) from all faxed or uploaded data such as pathology, scan and surgery reports.

Data Submission Requirements for Studies Coordinated by another Group

Data submission for studies not coordinated by SWOG require that data is sent directly to the Lead Protocol Organization (LPO) that developed the protocol. For a detailed explanation of these studies and their requirements, consult [Chapter 9 - Intergroup Studies](#). Otherwise, contact a data coordinator for assistance prior to intergroup data submission.

The Importance of Good Data Submission

ORPs are the key to successful and accurate study analysis. The collection of high-quality data starts at the institution level. Only when data collection is complete, timely, and accurate can study results maintain their validity and reliability. Some of the ways in which inaccurate, incomplete or missing data can compromise study results are listed below.

- Tumor response is the primary end-point of most Investigational New Drugs Phase II studies and a secondary end-point of many Phase III studies. To correctly assess a patient's response to therapy, the study chair must have accurate tumor measurements on all measurable lesions as well as complete information on all non-measurable disease. Also, Phase II studies have small sample sizes and are designed to terminate early when no responses are observed. Thus, these studies are particularly sensitive to errors in recording response, which may result in needless exposure of patients to an ineffective agent, early study closure, incorrectly labeling an agent as ineffective, or a biased response rate estimate.
- Survival is the primary endpoint for most Phase III studies as well as for some Phase II studies. Estimates of patient survival and differences between treatments can be misleading when follow-up is not current.
- Stratification factors must also be accurately reported. Randomized studies use procedures that are designed to guarantee balance between treatment assignments based on stratification factors. Thus, if incorrect values are given at the time of registration, these procedures are undermined. For non-randomized studies, incorrect stratification factors can result in the patient receiving an incorrect drug dosage.
- The quality control procedures conducted by the SDMC only involve data actually submitted by the institution. It is the purpose of the Quality Assurance (QA) program conducted by the SWOG Operations Office to check the accuracy of data submitted to the SDMC against documents contained in the institution's own hospital records. Please refer to [Chapter 1 – Audits](#).